REMARKS

Claims 1 to 35, 38 to 40, and 71 to 97, 112 and 113 are in the application. Claims 98 to 111 have been cancelled. Claims 1, 31-35, 71, and 73 have been amended. Claims 31 to 35 and 71 have been amended to depend upon Claim 1. Claim 35 has been amended to remove a duplicate formulation, to correct typographical errors, support lying in the specification in Example 37, page 42; and renumbered to be consistent with the amendment. The amendments to Claims 1 and 73 find support in the specification in the drawings, such as Figure 11, or in the specification on page 19, lines 15 and 16; and on Page 3, lines 25 to 33. No new matter is believed added.

Rejection of Claims under 35 USC §103

Claims 1 to 35, 38 to 41 and 71 to 111 are rejected under 35 U.S.C. § 103(a) as being obvious over Hatano et al. US Patent No. 6,309,666 ('666) in view of Lehmann et al. US Patent No. 5,705,189 ('189), hereinafter Lehmann I, and Lehmann et al. (US Patent No. 5,644,011 ('011), hereinafter Lehmann II. Applicants respectfully traverse this rejection.

Claims 112 and 113 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hatano et al. US Patent No. 6,309,666 ('666) in view of Lehmann I. (US Patent No. 5,705,189), and Lehmann II (US Patent No. 5,644,011). Applicants respectfully traverse this rejection.

The Examiner comments that "there is sufficient motivation within the prior art for combining the prior art references. Thus one of ordinary skill in the art would be motivated to combine the reference to incorporate the molding techniques of the Lehmann I patent into the disclosure of the Hatano et al patent in order to give one of ordinary skill in the art a greater degree of control in fashioning capsules that exhibit a particularly desired release characteristic". (Page 4, Office Action, 2nd ¶)

As extensively commented on by Applicants in previous responses the Hatano et al. patent, the primary reference in this rejection, does not use methacrylate copolymers in the same manner as does Applicants. It is not simply the materials, but the way in which the materials have been used. Claim 1, even prior to the amendments made herein characterized an article

which had a shell wall composed of a particular formulation. That formulation was not taught by Hatano et al, nor that a capsule shell wall would be composed of this material. The secondary references of Lehman I and II have been used by the Examiner to say that the acrylic and/or methacrylic articles such as capsule shells could be made. The skilled artisan would have this motivation to combine the teachings of Hatano et al. with Lehman I and II to achieve "fashioning capsules that exhibit a particularly desired release characteristic".

Contrary to the Examiner's statements, there is no motivation to take the primary reference and modify it by the teachings of the secondary references since they are not concerned with the same teachings. The Lehman II patent, '011 is solely concerned with particular Eudragit copolymers as a coating agent. There is no disclosure or teaching that the copolymers described therein would be used for producing an extruded material which is formed into a capsule shell wall or subunit. The formulations of Lehman II are taught as coating agents which are resistant to gastric juices e.g. for use as controlled release agents. These coating agents are applied by coating pan methods, or fluidized bed methods (column 4, lines 42 – 43). As such the copolymer mixture will include various additional excipients which aid in this coating process (column 4, lines 43-46). The additional excipients are not being taught for extrusion purposes to form molded articles.

Lehman I, the '189 patent discloses new copolymer materials which are primarily oriented for drug coating (Column 1, lines 61 to 67; and Column 2, lines 1 to 8). As the compositions described in the '189 patent have characteristics which make them thermoplastic, the materials can be molded, as described in Column 2, lines 20 to 36. However, as previously noted in Applicants earlier responses all of which are incorporated by reference herein, Column 2, lines 20 to 36 and the claims do **not** describe the composition used herein, known as Eudragit 4135F. This copolymer is described in Column 6, as emulsion polymer E2. The E2 polymer contains 10% methacrylic acid, not 16-40% w/w which is stated as being within the compositions having thermoplastic moldable characteristics.

Further, the E2 copolymer is not admixed with the additional agents stated on column 3, lines 62 to 67, and column 4, lines 1 and 2. Applicants specification, page 24, lines 1 to 3

also notes that the polymers described in the '189 patent have increased viscosity's relative to the blended compositions as used herein. There is no motivation, or teachings in any of the cited prior art references to change the viscosity of the compositions in the manner as claimed herein to achieve Applicants invention.

The Lehman I '189 patent is directed, as is Lehman II to compositions which are pH dependent and dissolve in the intestinal juices, not in the stomach, for use as controlled release coating agents.

Applicants have found that the compositions as modified by the teachings herein can be used in a pH independent manner. This is unexpected and not taught nor disclosed by Lehman I or Lehman II.

Applicants have amended the claims to better clarify that it is not a composition, but an article of manufacture which is being claimed. It is not a coating on a capsule shell as used in Hatano, but in fact is the capsule shell wall and/or linker composition.

While not addressed by the Examiner, neither Hatano, nor Lehman I or II describe or suggest a multicomponent dosage form made of the extruded material as claimed herein. There is no teaching or disclosure which provides for the linker subunits of claims 73 to 97.

The mere fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. MPEP § 2143.01 at 2100-131. There must be something in the prior art to suggest the desirability of the combination. *Id.; see also, In re Mills,* 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (Fed. Cir. 1990).

There is nothing in either Hatano or Lehman I or II to explain the incorporation of particular substituents, such as stearyl alcohol, or of a super disintegrant within the composition (see

Claims 9 and 10, 14, 16, 26, and 27) or a combination of a swellable solid and lactose, or super disintegrant (Claim 19), and those similar claims for the linker subunit.

Indeed, using the logic of the Examiner the Lehman et al. reference would teach the skilled artisan that such additional excipients and additives are not needed as the thermoplastic compositions are suitable for molding based solely upon the addition of glycerol monostearate as a mold release agent. This would suggest that the skilled person would not be motivated to make any substitution or additions whatsoever. This does not address the inclusion of the dissolution modifying excipients, the specific w/w% amounts of these excipients and the particular lubricants and surfactants as claimed by Applicants. As noted above, the Examiner has also not provided any basis for an article of manufacture which is the linker subunit. Although the linkercomposition is the same as that of the capsule shell wall, it is a linker subunit which is being claimed having that composition, not the composition itself. No cited references teach or describe this unit.

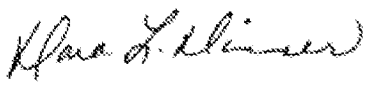
Therefore, the USPTO has failed to establish a *prima facie* case of obviousness for the claims as presented herein.

In view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §103 is respectfully requested

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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